K120930

Section 5 – Traditional 510(k) Notification:- Summary

OCT 26 2012

This Traditional 510(k) notification is to provide substantial equivalence for the Medtrade Products Ltd CHG Antibacterial Foam Patch, which is substantially equivalent to currently marketed devices intended for wound care.

Submitted by:- Medtrade Product Ltd
Electra House, Crewe Business Park
Crewe, Cheshire
CW1 6GL
United Kingdom

Contact:- Mrs Claire Ryan
Head of Regulatory & QA
Telephone: + 44(0)1270 500019
Fax:- + 44(0)1270 500045
Email: claire.ryan@medtrade.co.uk

Date prepared:- 26th March 2012

Proprietary Name: CHG Antibacterial Foam Patch

Common Name:- CHG Antibacterial Foam Dressing
CHG Antibacterial Patch
CHG Antibacterial Dressing
CHG Patch
CHG Dressing

Trade Names:- Not yet defined

Classification Name:- Dressing, Wound, Drug

Classification:- Unclassified

Product Code:- FRO

Legally marketed device(s) for substantial equivalence comparison:-
BIOPATCH, 510(k) # K003229, manufactured by Johnson and Johnson Wound Management.

Device Description:-
The Medtrade Product Ltd CHG Antibacterial Foam Patch consists of a hydrophilic Polyurethane absorbent foam with chlorhexidine gluconate (CHG) and a thin Polyurethane backing. The foam material absorbs up to eight times its own weight in fluid. The CHG present in the dressing inhibits or kills microorganisms on the surface of the dressing.

CHG Antibacterial Patch is available in the following sizes:-
1" DISK (2.5cm) 4.0mm center hole with radial slit.
¾" DISK (1.9cm) 1.5mm center hole with radial slit.
1" DISK (2.5cm) 7.0mm center hole with radial slit.

CHG Antibacterial Patches are packaged in individual pouches, then into shelf cartons with an instruction for use.

Indications for use:
Under the supervision of a healthcare professional CHG Antibacterial Foam Patch is intended for use as a hydrophilic foam patch that is used to absorb exudates and to cover the peri-wound area of a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: IV catheters, central venous lines, arterial catheters, dialysis catheters, midline catheters, drains, chest tubes, externally placed orthopaedic pins, and epidural catheters.

In-vitro Testing:-
In-vitro Antibacterial data has shown that CHG Antibacterial Foam Patch reduces or inhibits microbial colonization in the dressing. In vitro CHG Antibacterial Foam Patch has demonstrated a Log 4 reduction and has been shown to kill the following organisms, over a 7 day period.

Staphylococcus aureus (MRSA) NCTC 13142 – Gram Positive Bacterium
Escherichia coli ATCC 8739 – Gram Negative Bacterium
Pseudomonas aeruginosa ATCC 9027 – Gram Negative Bacterium
Enterococcus faecalis NCTC 12201 – Gram Positive Bacterium
Staphylococcus aureus ATCC 6538 – Gram Positive Bacterium

Manufacturing:-
CHG Antibacterial Foam Patch is manufactured according to the product specifications and under good manufacturing practices (GMP). A risk analysis has been performed in accordance with BS EN ISO 14971 to identify possible failure mode during manufacturing and design. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode.

Medtrade Product Ltd, CHG Antibacterial Foam Patch meets all the established specifications prior to release to ensure the device is safe, effective and correctly labeled for its intended use.

Testing:-
Performance data for the CHG Antibacterial Foam Patch have been established using antibacterial and bench testing. The biocompatibility of CHG Antibacterial Foam Patch has demonstrated to be in compliance with the requirements of BS EN ISO 10993-1 (Biological Evaluation of Medical Devices). Sterilisation validation has been performed in compliance with harmonised standards. The biocompatibility and performance testing for the CHG Antibacterial Foam Patch have demonstrated that the device is safe and effective for the indications of use.

Statement of Substantial Equivalence:-
The indication for use, performance testing and antibacterial activity for the CHG Antibacterial Foam Patch are substantially equivalent to the predicate device; BIOPATCH, 510(k) # K003229, cleared October 26, 2001, manufactured by Johnson & Johnson, as both products are absorbent polyurethane foams with the addition of CHG as an antibacterial.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 26 2012

Medtech Products, Limited
% Ms. Clare Ryan
Head of Regulatory and Quality Affairs
Electra House, Crewe Business
Cheshire, United Kingdom CWI 6GL

Re: K120930
Trade/Device Name: CHG Antibacterial Foam Patch
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 12, 2012
Received: October 16, 2012

Dear Ms. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120930

Device Name: **CHG Antibacterial Foam Patch**

Indications for Use:

Under the supervision of a healthcare professional CHG Antibacterial Foam Patch is intended for use as:

A hydrophilic foam patch that is used to absorb exudates and to cover the peri-wound area of a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: IV catheters, central venous lines, arterial catheters, dialysis catheters, midline catheters, drains, chest tubes, externally placed orthopaedic pins, and epidural catheters.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120930